

(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications.

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control.

(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).

§ 493.1241 Condition: General immunology.

To meet the quality control requirements for general immunology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control.

(b) The laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.

(c) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet—

(1) The HIV testing requirements of 21 CFR 610.45; and

(2) Hepatitis testing requirements of 21 CFR 610.40.

§ 493.1243 Condition: Chemistry.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1245 through 493.1249 of this subpart for the subspecialties for which it is certified under the specialty of chemistry.

§ 493.1245 Condition: Routine chemistry.

To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221. All quality control activities must be documented. In addition, for blood gas analyses, the laboratory must—

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;

(b) Test one sample of control material each eight hours of testing;

(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing; and

(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

§ 493.1247 Condition: Endocrinology.

To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

§ 493.1249 Condition: Toxicology.

To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented. In addition, for drug abuse screening using thin layer chromatography—